



European Monitoring Centre
for Drugs and Drug Addiction



Republic of Serbia
MINISTRY OF HEALTH

Serbia

Early warning system profile

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Introduction: definition and objectives

In accordance with the requirements of the European Union (EU) accession process, in 2016 the Serbian government called for the establishment of a national early warning system (NEWS) in Serbia. The need to develop the Serbian NEWS is mentioned in Chapter 4 of the Strategy on the Prevention of Drug Abuse for the period 2014-21, is further detailed in the action plan for the implementation of the Strategy for the period 2014-17, and is a part of the action plan for Chapter 24 of the EU acquis.

During the process of defining the structure, objectives and working methods of the Serbian NEWS, recommendations from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) as well as the experience of EU Member States were considered.

The Ministry of Health of Serbia has been leading the process of setting up the NEWS since 2017. In Serbia, the Centre for Drugs Monitoring and Drugs Addiction has been at the forefront of launching the activities and the development of the system. The EMCDDA, within its technical cooperation projects funded by the Instrument of Pre-accession Assistance (IPA) ⁽¹⁾, together with the Technical Assistance and Information Exchange (TAIEX) programme, supported the Serbian government, and the activities were carried out in close cooperation with the Office of Drugs of the Republic of Croatia in 2017.

The legal basis for the NEWS in Serbia is the Law on Psychoactive Controlled Substances ⁽²⁾. The Law on Amendments to the Law on Psychoactive Controlled Substances ⁽³⁾ was adopted by the Serbian parliament in July 2018, and this law includes the new psychoactive

substances (NPS) definition used in Regulation (EU) 2017/2101 ⁽⁴⁾ and Directive (EU) 2017/2103 ⁽⁵⁾.

The Early Warning System Protocol, to be implemented in the event of discovery of NPS in the Republic of Serbia, and which was agreed by all NEWS partners in January 2019, defines the composition of the network, the role of the partners, the main tasks and the reporting tools and working modalities of the system.

The Serbian NEWS aims:

- to monitor and collect information on the appearance of NPS in Serbia and to respond rapidly to these substances;
- to contribute to information exchange with the relevant structures at the European level;
- to assess the risks of NPS;
- to control and reduce the availability of NPS;
- to communicate risks to relevant national institutions and partners, and to contribute to harm reduction measures to reduce the negative health and social consequences of these substances among the high-risk population;
- to prevent the use of NPS.

Working modalities

The Centre for Monitoring Drugs and Drug Addiction was set up in the Ministry of Health, in the sector for medications and medical devices, controlled psychoactive substances and precursors, within the Department for

⁽¹⁾ 'Further preparation of the IPA Beneficiaries for their participation in the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) activities' (EMCDDA-IPA5 project) and 'Stepwise integration of the IPA beneficiaries in the activities of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the Reitox Network' (EMCDDA-IPA6 project).

⁽²⁾ Official Gazette of Republic of Serbia, 99/10, 57/18. Law on Psychoactive Controlled Substances.

⁽³⁾ Official Gazette of Republic of Serbia, 99/10, 57/18. Law on Psychoactive Controlled Substances.

⁽⁴⁾ Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R2101>).

⁽⁵⁾ Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA (<https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32017L2103>).

Controlled Psychoactive Substances and Precursors. The Centre is responsible for coordinating the NEWS in Serbia, which includes establishing cooperation with national partners, further developing the NEWS, planning and monitoring the implementation of activities, collecting and disseminating information, and reporting and communicating with the EMCDDA. The Centre also nominates an early warning system correspondent to the European Early Warning System, and this person is responsible for liaising with the EMCDDA.

To fulfil its function in relation to the NEWS, the Centre for Monitoring Drugs and Drug Addiction has established a network of partners (the Serbian NEWS network). The network has national coverage and operates in the Republic of Serbia on four levels (see Table 1).

A national correspondent to the EMCDDA, with the assistance of an expert (a pharmacist by education), is responsible for performing NEWS-related tasks: timely reporting the emergence of new drugs to competent authorities at national and European levels; updating

TABLE 1
The participants of the Serbian NEWS

Levels	Institutions	Functions
Level 1 — coordination	Centre for Drugs Monitoring and Drugs Addiction	Take on overall coordination Further develop the NEWS Plan and oversee activities Collect and disseminate information Report to and communicate with the EMCDDA Represent Serbia in the European EWS network
	The national focal point for cooperation with the European Union Agency for Law Enforcement Cooperation (Europol)	Report to the Europol National Unit
Level 2 — the Commission for Psychoactive Controlled Substances	Ministry of Defence Ministry of Health Ministry of Youth and Sport Ministry of Education, Science and Technological Development Ministry of Justice Ministry of Labour, Social and Veterans Affairs Ministry of Finance Ministry of Culture and Information Security Information Agency Ministry of Internal affairs Individual experts	Advise the Centre: <ul style="list-style-type: none"> • on general policy with regard to the NEWS • on the communication strategy • on the development of the NEWS Conduct national risk assessment Discuss developments and trends Propose measures to control NPS Contribute to the preparation of working documents and other content-related documents
Level 3 — the central network of early warning systems	Key state institutions involved in Level 2	Assist the Centre in the dissemination and collection of information relevant to the NEWS within their remit Continuously monitor trends in their field of work Collect relevant information and report it to the Monitoring Centre Disseminate information received from the Monitoring Centre
Level 4 — customers of the NEWS	General population, media, non-governmental organisations, drug users and other risk groups, and representatives of local self-government	Potential information source Potential beneficiary of the information generated by the NEWS Beneficiary of the measures taken by the NEWS Based on effective communication (e.g. expert platforms, publications on emerging trends and risks, helplines, internet forums, media alerts)

the list of psychoactive controlled substances; drafting reports to the EMCDDA, as requested; and communicating with relevant national institutions. The language of communication with NEWS partners is Serbian, while the language of communication with the EMCDDA is English.

Core functions and information flows

The process of information exchange in the NEWS is bidirectional. This means that the national partners provide the EMCDDA and Europol with information, and receive information from EU agencies. In addition, the process involves exchanging information with the International Narcotics Control Board and the World Health Organization.

All risk communications, including formal notifications on NPS, received from the European EWS are transmitted to the Commission for Psychoactive Controlled Substances for risk assessment and decision-making.

The information received through the European EWS is transmitted to all partners unchanged. However, in the future, the Serbian NEWS would like to develop more targeted information for dissemination to specific partner groups.

Information is usually exchanged at the national level by email, but it may also be conveyed at meetings that bring together experts from a specific area. The aim is to hold meetings at least once a month. If urgent information needs to be addressed, ad-hoc meetings can be also arranged.

Overall, the review of the NEWS functioning carried out in 2018 by the EMCDDA team indicates that the partner institutions are aware of their role and mandate within the Serbian NEWS. However, future efforts should be made to increase the information coming from institutions at Levels 3 and 4 (Table 1). The facilitation of the information exchange through a wider network of partners, with a view to broadening the scope of the information exchanged (i.e. information related to health facilities, customs, police administrations, schools, etc.), is planned in the near future.

The key laboratories

There are four key institutions that have their relevant laboratories and networks in Serbia that may detect the appearance of NPS.

The **National Poison Control Centre of the Military Medical Academy (NPCC)**, part of the Ministry of Defence, comprises two units, as follows:

- The Department of Toxicological Chemistry (OTH) of the Institute of Toxicology and Pharmacology is equipped to screen for a number of NPS in ante- and post-mortem biological matrices (urine and blood). It can also identify NPS from physical samples that have been recovered from patients with suspected acute poisoning (resulting from the ingestion of, for example, powder, tablets, plant material or other similar materials). Instrumentation/techniques routinely employed in the analysis of NPS samples include Gas chromatography – mass spectrometry, Liquid chromatography – mass spectrometry, Liquid chromatography – tandem mass spectrometry, Gas chromatography – tandem mass spectrometry and High performance liquid chromatography. The libraries used include TOXIS, MASSLINKS and NIST .
- The Clinic for Emergency and Clinical Toxicology has as its main tasks the prevention, diagnosis and treatment of acute poisonings; dissemination of information; the provision of specialised support to health institutions and populations regarding the toxic effects of chemical substances (psychoactive substances, including NPS); and diagnosis and treatment of conditions linked to the use of toxic substances.

The NPCC implements a training course on clinical toxicology at the Faculty of Medicine at the Military Medical Academy. Its ongoing task is the prevention of toxicological events through continuous cooperation with relevant ministries in the country, preventive activities involving the production of information materials on toxic effects, first aid measures and the management of acute poisoning.

The **National Centre for Criminal Forensics in the Ministry of Internal Affairs** has a central laboratory located in Belgrade and coordinates the work of three regional police laboratories, in Novi Sad, Niš and Užice.

The roles of these laboratories are to identify the seized substances; to assist investigations of drug-related crimes through analytical monitoring; to gather information and to plan and implement complex operational processing; to improve the methodology of operational work; to cooperate with other bodies, organisations and institutions dealing with related tasks; to participate in international cooperation on drug issues, in particular the dismantling of international drug trafficking chains and broader

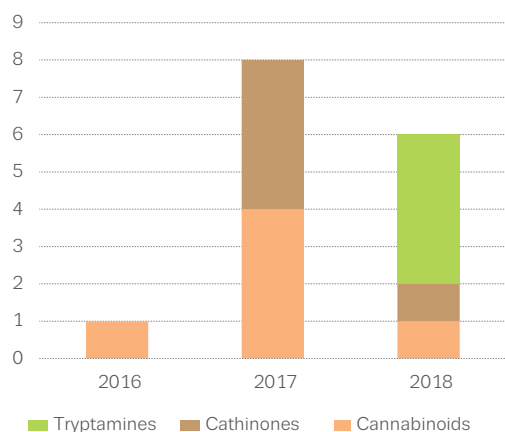
actions related to drug-related offences committed by organised crime groups; to suppress narcotics by targeting so-called 'street' sales and the distribution of drugs; to address issues of prevention in cooperation with other interested social entities; and to monitor trends in the sale and consumption of drugs, the number and structure of offenders and users and, when necessary, to develop of preventive action plans and perform other tasks within the scope of the ministry. The central laboratory is a member of the European Network of Forensic Science Institutes (ENFSI) and participates in the United Nations Office on Drugs and Crime (UNODC) proficiency exercises. The central laboratory and its national members support the work of not only the Ministry of the Interior but also Customs. Instrumentation/techniques routinely employed in the analysis of NPS samples in these laboratories include GC-MS and FTIR. The routinely used libraries include IR ENFSI, IR SWGDRUG, MS ENFSI, MS SWGDRUG, NIST, and other available commercial libraries.

The **Security Information Agency** is responsible for research and the collection, processing and evaluation of data and information that is important to the security of the Republic of Serbia, especially in the domains of organised crime and terrorism, and in relation to activities related to the unauthorised production and marketing of illicit substances, illegal trafficking in weapons, ammunition or explosive materials, trafficking in human beings, forgery, money laundering and corruption. The Agency, among other tasks, performs all kinds of analyses and super-analysis for detecting the presence of psychoactive substances in seized material from illegal trafficking and illegal production, to suppress international organised crime and terrorism; ensures compliance with the demands of judicial and other state authorities, and with the needs of third parties. One of the roles of the Agency is to carry out research, develop capacity-building activities in the field of chemistry and conduct physicochemical investigations of psychoactive

substances for the purpose of identifying and determining their possible misuse. The instrumentation/techniques routinely employed in the analysis of NPS samples are HS-GC-EI-MS/MS, HS-GS-CI-MS/MS, ATR-FTIR, Raman spectroscopy, HPLC-DAD-RI, IC, melting point and GC-FID (Kovats retention index). The laboratory routinely uses UNODC libraries, MS SWGDRUG and some others.

The **National Reference Laboratory (NRL) for Identification and Testing of Psychoactive Controlled Substances** at the Institute of Forensic Medicine within the Faculty of Medicine in Belgrade cooperates with laboratories in the Forensic Medicine Institutes in Novi Sad, Kragujevac and Niš. These laboratories analyse biological matrices (urine, blood, hair) taken from deceased persons and test samples for the presence of psychoactive substances. Testing is normally undertaken at the request of the competent Prosecutor's Office, usually in cases such as injuries, suicides, murders or other suspected unnatural deaths. The NRL may also analyse biological samples taken from victims of abuse, domestic violence and rape, as well as from offenders, if substance misuse is suspected. The reference laboratory has the capacity to perform an analysis of physical samples of seizures (e.g. powders, tablets, plants, liquids, residues recovered from syringes) as well as biological samples of living persons (blood, urine, hair) and biological samples of deceased patients (biological fluids, tissues and organs). This laboratory routinely employs a variety of instrumentation/techniques in the analysis of NPS samples (e.g. GC-MS, GC-MS/MS, LC-MS/MS, LC-QTOF/MS) and uses libraries such as SWGDRUG, PMW_tox3.l, Wiley 7NIST05.L and the Personal Compound and Database Library for LC-QTOF/MS. The laboratory participates in international interlaboratory cooperation with the UNODC Drug Discovery Unit and is also a member of the International Association of Forensic Toxicologists.

FIGURE 2
Number of NPS detected in Serbia in 2016-2018, classified by substance group



Note: Data provided by the National Centre for Criminal Forensics, the National Reference Laboratory for Identification and Testing of Psychoactive Substances, and the Security Information Agency.

Data collection tools

The legal status of NPS that are not on the list of psychoactive controlled substances is frequently unclear. Only a chemical analysis can reliably identify which substance has been seized/detected. In practice, the Serbian police seize all substances that they suspect are illicit or are a controlled psychoactive drug.

In Serbia, laboratories of all four institutions have detected and reported NPS (see Figure 2 and Table 2). When a laboratory detects an NPS, it submits an EMCDDA-Europol Reporting Form to the Ministry of Health. This contains information on the institution sending the report, the place of seizure/detection, the name of the substance, the quantity seized or detected, and the composition and appearance of the sample. The coordinator at the Ministry of Health submits these reports to the EMCDDA and disseminates the information to all network partners.

The Centre for Drugs Monitoring and Drugs Addiction is working on a national online database for detected substances. Currently, information on all substances detected — name, classification, information about detection, chemical and analytical characteristics, pharmacology, toxicology and chemical structure — is recorded in a Microsoft Excel file.

TABLE 2
NPS detected in Serbia by substance group

Tryptamines	Synthetic cannabinoids	Synthetic cathinones
1P-LSD	5F-MDMB-PINACA	α-Pyrrolidinohexanophenone (α-PHP or PV-7) (four detections; in one of the detections FUB-AMB was also identified)
AL-LAD	5-Fluoro-MDMB-PICA	4-Chloroethcathinone
4-HO-MIPT	AMB-CHMICA	NEH
4-AcO-DMT	CUMYL-5F-PINACA	Ephylone
	SGT 25	
	FUB-AMB	
	AMB-FUBINACA	

Setting-up a national risk assessment procedure

The national risk assessment procedure in Serbia is largely based on the experiences of neighbouring countries and has been set up with the support of TAIEX.

The Government Commission for Psychoactive Controlled Substances, an advisory body for the NEWS, includes a number of ministries (see Figure 1) and is responsible for conducting the national risk assessment. This Commission meets at least twice a year; however, if needed, its meetings may also be convened on an ad-hoc basis.

The risk assessment of NPS is performed by a team of experts from the Commission for Psychoactive Controlled Substances and is based on the review of available scientific literature and on evidence of the potential use of these substances.

In accordance with the Law on Psychoactive Control Substances, as soon as the risk assessment is completed, and following its results, the Commission may propose the adoption of changes to the Rulebook on the Establishment of the List of Psychoactive Controlled Substances to the Ministry of Health.

A case study

The Ministry of Internal Affairs seized a sample of light-beige powder in Belgrade, amounting to around 1.97 g. In addition, in July 2017, the Customs service seized, from the Belgrade Post Office, two zip-locked plastic bags containing approximately 70 g of powder (Figure 4).

Forensic analyses revealed that both samples contained α -pyrrolidinohexanophenone, also known as α -PHP or PV-7, while the seizure made by Customs contained, in addition, FUB-AMB. The seized bags were labelled as 'not for human consumption'.

To date there have been no reports in Serbia on the health consequences of the use of these two substances.

FIGURE 4
Two bags containing α -PHP and FUB-AMB seized at the Customs Post Office in Belgrade in 2017



Source: Image provided by Customs Post Office Belgrade, Serbia.
Photo: © Serbian Customs Administration.